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Endoappliance for hip joint restoration

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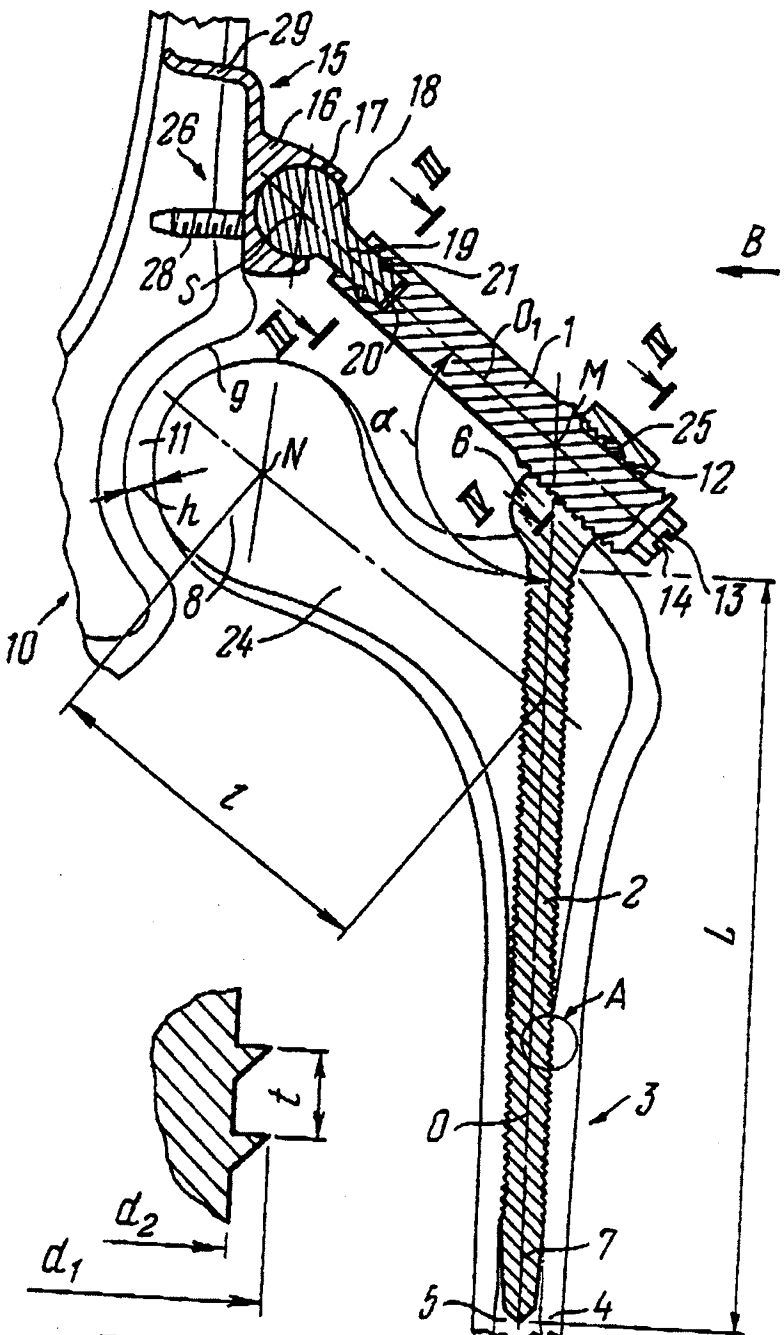
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FIG.2

FIG.1

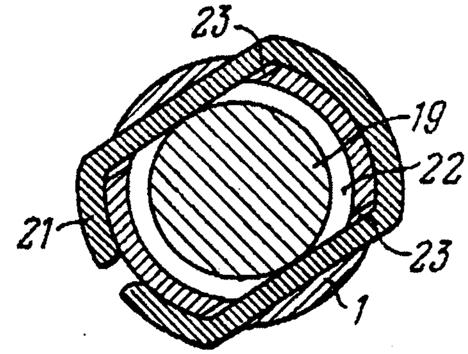


FIG. 3

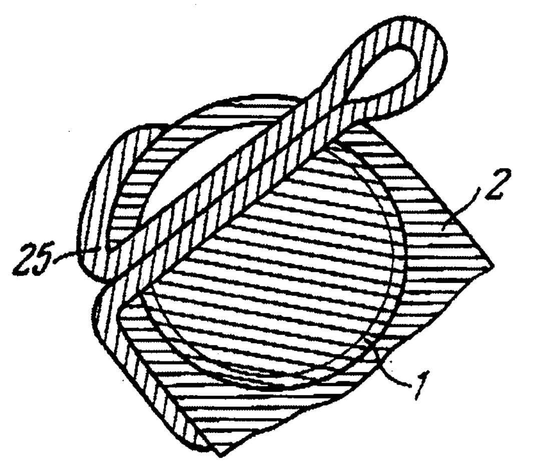
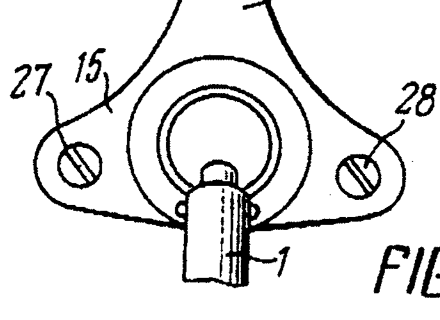


FIG. 4



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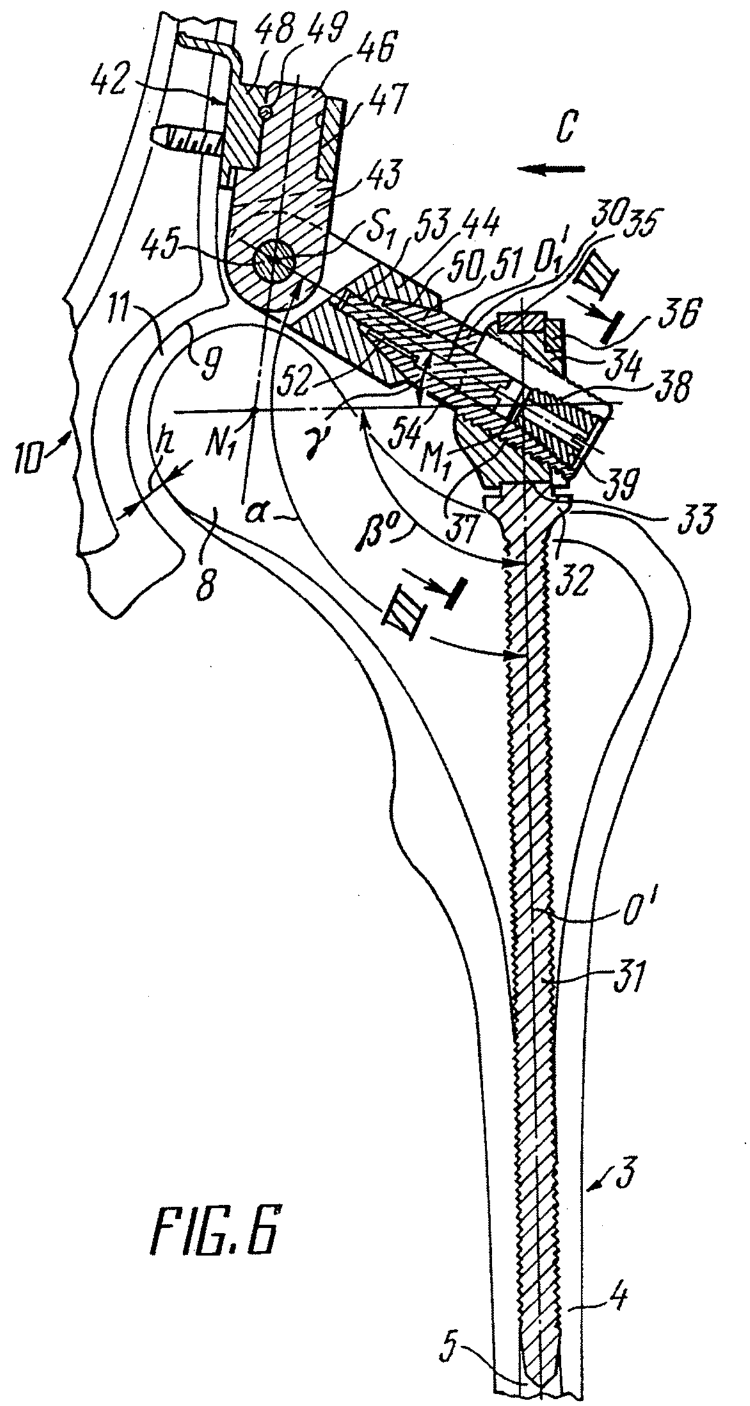

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FIG. 6

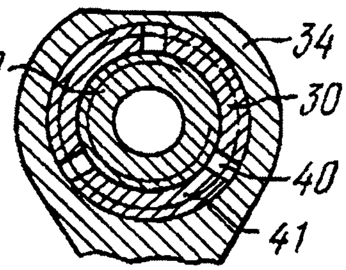

FIG.7

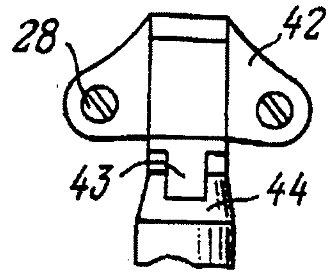

FIG.8

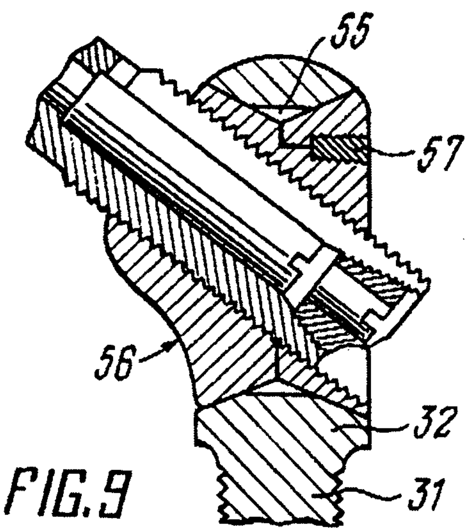

FIG.9

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ENDOAPPLIANCE FOR HIP JOINT RESTORATION

Technical Field

The present invention relates generally to medicine, more specifically to surgery, orthopedics and traumatology and is particularly concerned with implantable devices for treatment of human locomotorium that is, an endoappliance for hip joint restoration.

The hip joint is known to be the most important and vulnerable in human locomotorium, since loads imposed on said joint are five times and more human body weight. In addition, the femoral head should be movable enough in the cotyloid cavity so as to provide adequate mobility of man's lower limbs as for their flexion-extension, adduction-abduction, and rotation. Angular displacement of a sound femoral head fall within an adequately wide range, viz., angle of flexion, 120 to 150 degrees; angle of extension, 10 to 15 degrees; angle of adduction, 25 to 30 degrees; angle of abduction, 25 to 30 degrees; angle of outward rotation, 60 to 80 degrees; angle of inward rotation, 40 to 70 degrees.

Angle of flexion-extension implies an angle between the axis of the diaphysis and the body trunk vertical axis in a sagittal plane. Angle of adduction-abduction means an angle between the axis of the diaphysis and the body trunk vertical axis in a frontal plane.

Angle of rotation is in fact an angle of rotation substantially about a vertical axis. All the abovesaid angles equal zero with the hip joint in the initial physiological position, i.e., when the diaphyseal axis makes up an angle of 87 degrees with the body trunk vertical axis.

Degenerative-dystrophic affections of the hip joint occur much more frequently than the similar diseases of other joints of the locomotorium in human beings. Thus, the incidence of coxarthrosis is rather high in the Soviet Union, reaching to 3 or 4 percent of the total able-bodied population.

Coxarthrosis owes its origin to destructive changes in the hip joint and involves a patient in especially grave distress, renders him disabled and unable to look after himself in everyday life, and is causative of permanent pain.

The heretofore-known methods for treatment of hip joint pathologies concerned with its destructive changes, can be classified as conservative and surgical.

Conservative methods cover physical therapy procedures without axial loads upon the limb, load relief of the limb by skeletal bed traction or due to temporary immobilization by virtue of plaster-of-Paris, physiotherapeutic procedures stimulating regional circulation in the hip joint and in the limb as a whole, massage, electrophoresis and medicaments.

However, conservative treatment methods can at the most only hold back further development of the degenerative-dystrophic process, only at initial stages thereof. This is concerned with early diagnosis of coxarthrosis, which is fairly complicated only for experienced specialists in the disease. Therefore it is more frequently in therapeutic practice to encounter with

state II-II degenerative-dystrophic process, that is, when X-ray examination of a patient detects not only considerable constriction of the articular interstice but also deformation of the contours of the femoral head and cotyloid cavity. At present, surgical treatment methods are given apparent preference as being the most intense and efficacious ones. Among such methods are osteotomy, arthrodesis, arthroplasty, osseous arthroplasty, endoprosthetic restoration of articular surfaces, surgery on soft tissues, unilateral endoprosthetic restoration (such restoration of the femoral bone proximal end or of the cotyloid cavity), bilateral (total) endoprosthetic restoration (such restoration of the femoral bone proximal end and of the cotyloid cavity), involving the use of caliper distraction apparatus.

It is the total endoprosthetic restoration that is given conspicuous preference in worldwide surgical practice over all other surgical methods of treatment of coxarthrosis, which has for an ultimate objective to restore the lower limb locomotor function. All the rest of the operative techniques mentioned above (i.e., osteotomy and arthrodesis) are essentially palliative, that is, they only retard further development of the degenerative-dystrophic process for a certain length of time so that eventually orthopedic surgeons resort to the total endoprosthetic restoration.

The essence of the aforesaid method resides in complete concurrent replacement of the resected femoral bone end and the resected cotyloid cavity by endoprostheses made of a material indifferent to organism's body fluids (plastics, metal, ceramics).

However, serviceability of such endoprostheses are liable to deteriorate due to mechanical wear and tear in the course of service life, that is, the effective life

of the endoprosthesis is as low as one-half or one-third the patient's life, whereas replacement of an endoprosthesis is an arduous task on account of a deficit of the bone tissue, since part of the biological materials surrounding the injured tissues, are to be removed. This in turn results in loosened attachment of a new prosthetic structure and in postoperative complications arising after repeated surgical interventions. That is why orthopedic surgeons are apt to perform endoprosthetic restoration mostly in advanced-aged patients.

Besides, such surgeries are highly traumatic and dangerous. The vital risk is especially high in advanced age; such surgery is largely fraught with complications that involve total removal of the endoprosthesis and hence complete loss of the lower limb functions.

More promising is a surgical treatment method based on ability of the osseous and cartilaginous tissues to regenerate and on the use of caliper distraction apparatus aimed at relieving the joint of load the supporting ability and mobility of the lower limb and the mobility of the hip joint remaining unaffected. In this case an important condition of successful hip joint restoration is ability of the caliper distraction apparatus to provide an optimum position of the femoral head in the cotyloid cavity with a required amount of the articular interstice.

At present there exist two types of caliper distraction apparatus, viz., apparatus partly implantable into patient's body and those completely implantable thereinto.

Practical application of caliper distraction apparatus cuts down the bedrest period, and the patient starts to load the lower limb operated upon in a shorter period of time after surgery. Activated muscular

contractions improve lympho- and blood supply of the affected joint area, promote prompt resolving of the decay products and those of hemorrhages and edemas, ameliorate tissue metabolism and coursing of the reparative processes, restore disturbed reflex connections, recover elasticity of the ligamentous-bursal apparatus, and intensifies production of the synovial fluid.

All mentioned above arrest further progress of the degenerative-dystrophic process and eliminate pain syndrome; besides, a growth of the osseous tissue and the hyaline cartilage coating of the articular ends is observed in the articular interstice established between the surface of the femoral head and that of the cotyloid cavity i.e., there occurs a process of formation of a normal natural joint.

One state-of-the-art endoapparatus for prosthetic restoration of the hip joint (SU, A, 1251889) is known to comprise a rod whose one end is linked to a means for holding to the hipbone, while its other end is articulated to a means for holding to the femoral bone.

The means for holding to the hipbone and the means for holding to the femoral bone are practically similar. Each of said means is shaped as an arcuate comb having the pointed teeth arranged on its concave surface, while a convex surface of the combs carries sleeves fixed in place thereon, the axes of said sleeves being arranged symmetrically with respect to the ends of the combs. The axis of the sleeve fixed on the comb that is aimed at being held on the hipbone is arranged radially, while the axis of the sleeve made fast on the comb intended to be held on the femoral bone lies in its radial plane and makes an acute angle with the radius. The rod is axially movable, with one of its ends, in the sleeve, which is fixed on the comb intended to be held to the hipbone, while the other rod end is shaped as a spherical head.

The sleeve made fast on the comb, which is aimed to be held to the femoral bone, accommodates an insert having a spherical recess adapted to accept the rod head forming a spherical joint. Besides, both of the sleeves are provided with two compression springs, of which one is interposed between the insert and the comb, while the other, between the rod and the other comb, said springs being adapted for dynamic releasing of the hip joint.

When implanting such an endoapparatus for hip joint restoration, one of the combs is put on the hipbone in its supra-aoetabular region, while the other sleeve is put on the femoral neck so that both of the sleeves are coaxial and the sleeves and rod are situated above the epiphysis in a position close to a vertical one.

Such a construction arrangement of the endoapparatus discussed above makes it possible to use said endoapparatus only for partly reducing the load upon the hip joint and is practically instrumental only in releasing said joint of the effect of muscular spasms arising in the course of the disease and amounting to as high as 80 kg. Thus, the treatment method based on the use of said endoapparatus is essentially an alternative to surgery on the soft tissue, in particular, to Foss' operation (the so-called 'pendulous hip joint').

In addition, attachment of the comb on the femoral neck creates in said area the zones of stress concentration in the bone tissue, which are causative of necrosis and destruction of the femolar neck that has been affected by the disease.

It should be pointed out that said endoapparatus fails to provide rigid fixing of the femoral head in position in the cotyloid cavity, i.e., to adjust for a required means of the articular interstice.

One more prior-art endoapparatus for restoration of the hip joint (GB, A, 1507953) is known to serve

substantially as a supporting structure for the lower limb and performing the functions of the hip joint for its complete releasing for the reconstruction period. The endoapparatus mentioned above comprises a rod capable of sustaining loads that are essentially equal to the maximum loads sustained by patient's lower limb, said rod being connected with one of its ends to a means for holding to the femoral bone and with the other end articulated to a means for holding to the hipbone.

The means for holding to the hipbone and the means for holding to the femoral bone are constructionally similar and rather sophisticated, since each of these comprises two arcuate members, which contact each other with one of their ends, while the other ends thereof are directed oppositely.

The rod articulated joint is shaped as an arcuate groove adapted to be placed above the femoral neck and to accept a spherical head provided at one of the rod ends with a possibility of motion lengthwise the groove and of rotation about the centre of said head. The other rod end is bent downwards and connected to the means for holding to the femoral bone. When the endoapparatus is implanted into the hip joint the rod is situated in front of the femoral bone, while the arcuate members of the means for holding to the femoral bone are located inside the diaphysis. In order to insert said members into the femoral bone a hole is to be made in the cortical layer of the bone, which substantially weakens the femoral bone at the place of stress concentration.

The endoapparatus of the aforementioned construction arrangement is cantilevered to the femoral bone, which gives rise to an overturning moment, which adds to the loads upon the femoral bone. In this case the physiological loads taken up by a group of muscles that actuate the lower limb, are inconsistent with the

physiological loads imposed upon a sound hip joint, which leads inescapably to reconstruction of the muscular corset. To fix the endoapparatus on the hipbone a hole is made in the latter bone, into which are inserted the arcuate members resting upon the hipbone at two points. The arcuate members of the means for holding to the hipbone are linked to the distraction mechanism, which is adapted to change, during surgery for endoapparatus implantation, a distance between the centre of rod head and the bearing points of the arcuate members in order to adjust a preset amount of the articular interstice. The distraction mechanism is of a sophisticated construction arrangement and the process for adjusting the amount of the articular interstice is rather complicated and takes up much operative time.

Thus, provision of the means for holding the rod to femoral bone, in the aforediscussed endoapparatus for hip joint restoration, as two arcuate members having each substantially two points of contact with the femoral bone, weakens the femoral bone, results in stress concentration at the points of contact, imposes additional loads upon the femoral bone, which affects adversely the results of treatment, and leads to resorption of the bone tissue and destabilization of the endoapparatus position, which cuts down the period of its application.

It is an aim of the invention to provide an endoappliance for hip joint restoration having such a structural arrangement and embodiment of a means for holding said endoapparatus to the femoral bone which establishes specific loads taken up by the osseous tissue of the femoral bone that are not destructive to the latter and which are close to physiological loads taken up by a sound lower limb, as to the nature and amount, within a period of complete hip joint restoration.

According to the present invention there is provided an endoappliance for hip joint restoration, comprising a first rod capable of sustaining loads that are substantially equal to the maximum loads taken up by patient's lower limb, the rod being connected through one of its ends to a means for holding the rod to a femoral bone whereas the other end thereof is articulated to a means for holding the rod to a hipbone, characterised in that the means for holding the rod to the femoral bone is haped as a second rod adapted to be fitted inside the femoral bone substantially along the axis of a diaphysis and arranged at an angle to the first rod, the angle being substantially equal to the cervicodiaphyseal angle.

Such a rather simple construction arrangement of an endoappliance for hip joint restoration having a means for its holding to the hip joint shaped as a rod aimed at being fitted into the femoral bone along the diaphyseal axis and arranged at an angle to the main rod that is substantially equal to the cervicodiaphyseal angle predetermines positioning of the main rod above the femoral neck with its axis arranged substantially parallel to the epiphyseal axis in a plane passing through the diaphyseal axis and the centre of the articular head, wherein the nature and amount of loads acting upon the lower limb corresponds to the physiological loads taken up by a second lower limb. In this case the hip joint is completely released, which provides favourable conditions for its restoration.

Moreover, arrangement of an additional rod along the diaphyseal axis reduces specific loads upon the osseous tissue of the femoral bone to amounts at which the body tissue experience no deformations causative of pathologies. The femoral bone proves to be intact and not weakened in the zone of stress concentration situated at

the place of contact of the additional rod end with the cortical bone layer, since the hole for the additional rod to pass is situated in the cortical layer of the trochanteric fossa.

Such a means for holding the endoappliance to the femoral bone provides for rigid fixing of the femoral head centre in position in the cotyloid cavity and hence retains a preset amount of the articular interstice.

It is expedient that in an endoappliance for hip joint restoration the length of that portion of the additional rod which is accommodated in the femoral bone, be substantially equal to half the length of the patient's femoral bone.

It is desirable that in an endoappliance for hip joint restoration, with a view to facilitating insertion of the additional rod into the femoral bone, a thread be provided on the additional rod on its portion situated inside the femoral body.

It is beneficial that in an endoappliance for hip joint restoration the main rod be connected to the additional rod through a threaded joint enabling the main rod to move lengthwise its own axis. This facilitates and simplifies much adjustment of the amount of the articular interstice in the course of surgery.

It is favourable that in an endoappliance for hip joint restoration, with the purpose of fixing the main rod in a preselected position, a tapered hole be provided at the main rod end facing the threaded joint, said hole being situated along the axis of said rod, and at least three longitudinal slots arranged along the length of said tapered hole, and that a stop sleeve be fitted in said hole with the aid of a threaded joint.

In order to completely prevent the hip joint from contact with the cotyloid cavity during flexion-extension of the lower limb, it is expedient that in an

endoappliance for hip joint restoration the main and additional rods be interconnected through an articulated joint capable of rotating about an axis coplanar with the axes of both rods and arranged at such an angle to the axis of the additional rod that ensures setting of the articulated joint fulcrum, during implantation of the endoappliance, to a position, wherein it passes substantially through the centre of the femoral head.

It is reasonable that in an endoappliance for hip joint restoration the fulcrum of the articulated joint make up an angle of from 76 to 90 degrees with the axis of the additional rod.

It is advantageous in an endoappliance for hip joint restoration that the articulated joint be shaped as a plain bearing having a tapered seating face.

In what follows the invention is illustrated in a detailed description of specific exemplary embodiments thereof with reference to the accompanying drawings, wherein:

Fig. 1 is a general longitudinal sectional view of an endoappliance for hip joint restoration, provided with a rod articulated to a means for holding said endoappliance to the hipbone with a possibility for said rod to rotate about a common point, with the femoral bone in an initial physiological position, according to the invention;

Fig. 2 is a scaled-up view of a unit A in Fig. 1;

Fig. 3 is a scaled-up view of a section taken along the line III-III in Fig. 1;

Fig. 4 is a scaled-up view of a section taken along the line IV-IV in Fig. 1;

Fig. 5 is a view facing the arrow B in Fig. 1 to partly represent the main rod of endoprosthesis,

according to the invention;

Fig. 6 is a general longitudinal sectional view of an alternative embodiment of an endoappliance for hip joint restoration having a main rod articulated to a means for holding to the hipbone and connected to a means for holding to the femoral bone, with the femoral bone in an initial physiological position, according to the invention;

Fig. 7 is a scaled-up view of a section taken along the line VII-VII in Fig. 6;

Fig. 8 is a view facing the arrow C in Fig. 6 to partly represent the main rod of the endoprosthesis, according to the invention; and

Fig. 9 is a scaled-up framentary longitudinal sectional view of a main rod and an additional rod at the place of their articulated joint shaped as a plain bearing having a tapered seating face, according to the invention.

Preferred Embodiment of the Invention

The endoappliance for hip joint restoration comprises a rod 1 (Fig. 1) predominantly of a round cross-section and capable of sustaining loads that are equal to the maximum loads exerted upon human's lower limb. The rod 1 may be made of a metal or alloy indifferent to human body fluid, in the capacity of which use is commonly made of, e.g., a titanium alloy. The amount of load applied to the rod 1 can reach 5 P, where P denotes patient's mass. As a rule, the diameter of the rod 1 ranges between 10 and 16 mm.

With one of its ends the rod 1 is connected to a means for holding to the femoral bone in the capacity of which is used another rod 2 adapted for insertion into the femoral bone 3, i.e., into a medullary canal 5 substantially along an axis 0 of a diaphysis 4 of the bone 3. The rod 2 makes up an angle α with the rod 1, the

magnitude of said angle being substantially equal to that of the cervicodiaphyseal angle and may range between 120 and 140 degrees.

The diameter of the rod 2 may range within 9.5 and 11 mm and is to be selected depending on the diameter of the medullary canal 5.

The length of the rod 2 should be such that its vacant end be situated in the middle portion of the diaphysis 4. The length L of that portion of the rod 2 which is accommodated inside the femoral bone 3, is substantially equal to half the length of the femoral bone 3 and ranges from 125 mm in children to 180 mm in adults. Such a length L provides for reduction of the specific loads applied to the osseous tissue of the femoral bone 3 down to the values at which said osseous tissue does not experience any pathological changes throughout the lapse of time the endoappliance resides in human organism.

A portion 7 of the rod 2 situated at the vacant end thereof is pointed so as to facilitate introduction of the rod 2 into the medullary canal 5. Besides, a thread is provided on the portion L of the rod 2, aimed at facilitating insertion of the rod 2 into the femoral bone 3 and at a uniform distribution of applied loads over the length of the femoral bone 3. It is expedient that said thread be of the butt type featuring a major diameter d_1 equal to 12 mm (Fig. 2), a minor diameter d_2 equal to 8.6 mm and a pitch t equal to 4 mm. Such a construction arrangement of the means for holding to the femoral bone 3 (Fig. 1) provides for rigid fixing of the position assumed by the centre N of the head 8 of the femoral bone 3 in a cotyloid cavity 9 of a hipbone 10 and hence contributes to retention of a preset amount of an articular interstice of the hip joint, since the butt thread prevents the rod 2 from axial displacement.

The rod 2 and the rod 1 are so interconnected

that the latter is movable lengthwise its own axis 0_1 and fixable in a preselected position, which adds substantially to the easiness and simplicity of the process for adjustment of the amount of the articular interstice 11.

Such an interconnection may be of any heretofore-known nature. In the present embodiment of an endoappliance for hip joint restoration use is made of a threaded joint between the rods 1 and 2 enabling the rod 1 to move lengthwise its axis 0_1. The portion 6 of the rod 2 is thickened and has a threaded hole 12 whose axis makes up an angle α with the axis 0 of the rod 2.

To facilitate movement of the rod 1, provision is made at its end extending from the threaded hole 12, for a shank 13 for wrench and for slots 14 for screwdriver.

The other end of the rod 1 is associated with a means for holding to the hipbone 10 through an articulated joint allowing the rod 1 to rotate about a common point (fulcrum) S.

The means for holding the rod 1 to the hipbone may be of any heretofore-known type. In a given embodiment of an endoappliance for hip joint restoration said means is essentially a plate 15 having at one end an expansion 16 with a spherical recess 17 which accepts a spherical head 18 of articulated (ball-and-socket) joint. The head 18 has a cylindrical shank 19 fitted in a blind axial hole 20 of the rod 1 and fixed therein with the aid of a check clamp 21 (Fig. 3) fitted in an annular groove 22 of the shank 19 and in two parallel openings 23 made in the rod 1.

The distance between the fulcrum of the articulated joint, i.e., the centre (fulcrum) S (Fig. 1) of the head 18, and a point M of intersection of the axes 0_1 and 0 of the respective rods 1 and 2 should be close to

the length of an epiphysis 24 between a centre N of the head 8 of the femoral bone 3 and the longitudinal axis of the medullary canal 5 of the femoral bone 3. Said distance SM should be such that, with the femoral bone 3 in the initial physiological position, the articular interstice 11 left between the head 8 of the femoral bone 3 and the cotyloid cavity 9 of the hipbone 10, when fitting the endoappliance in position, have an optimum amount necessary for the growth of the osseous tissue and restoration of the hip joint function. The amount h of the articular interstice 11 is set in the course of surgery for implanting the endoappliance individually for every particular patient by appropriately moving the rod 1 in the threaded joint 12. It approximates the amount of the interstice of a sound hip joint. A cotter pin 25 (Fig. 4) is provided for locking the rod 1 in a preselected position, siad cotter pin fitted in respective concentric holes made in the rods 1 and 2. The plate 15 (Fig. 1) is so positioned in a supra-acetabular region 26 of the hipbone 10 that a distance between the points S and H is the minimum possible. To fix the plate 15 in position two holes 27 (Fig. 5) are made therein, in which woodscrews 28 or dowel pins are fitted. The plate 15 should have such configuration as to provide its tightest adherence to the hipbone 10 (Fig 1).

A narrower end 29 of the plate 15 is bent towards the hipbone 10 and fitted in a hole made in the hipbone 10 in the course of surgery. Thus, the plate 15 is rigidly fixed in position on the hipbone 10 and hence the axis 0_1 of the rod 1 is fixed in position, too.

Besides, the plate 15 is to be fixed on the hipbone 10 in a position, wherein the axis 0_1 of the rod 1, with the femoral bone 3 in the initial physiological position, lies substantially in a plane passing through the axis of the medullary canal 5 and the centre N of the

head of the femoral bone 3. With the rod 1 in such a position the loads sustained by the lower limb correspond to the physiological load exerted upon a sound hip joint, which tells favourably on the treatment results.

Such a construction arrangement of the endoappliance for hip joint restoration is as simple as possible, retains strength of the osseous tissue, enables one to align one of the axis of rotation of the articulated joint with one of the three principal axes of hip joint rotation, and makes it possible to extend the scope of motion of the hip joint when rotated about the other two axes, i.e., in the case of abduction-adduction and flexion-extension, due to bringing the fulcrum of the articulated joint closer together with the fulcrum of the hip joint.

A sugical procedure for implantation of the proposed endoappliance for hip joint restoration is carried out as follows:

First the length of the epiphysis 24 (Fig. 1) is measured as against an X-ray photo, whereupon the appropriate standard size of the rod 1 is selected depending on said length, i.e., the rod length and diameter, as well as the required standard size of the rod 2.

Once a general preoperative treatment of the zone of surgery has been performed in a way similar to that carried out before surgery for implantation of the known endoapparatus for hip joint restoration, a hole is made in the cotyloid cavity cortical layer, said hole being arranged on the axis of the medullary canal 5. Then the rod 2 is inserted into said hole as far as its thickened portion 6 thrusts against the femoral bone 3, after which the rod 2 is rotated to assume a position, wherein the axis of the threaded hole 12 is located in a plane passing through the axis of the medullary canal 5

and the centre N of the head 8 of the femoral bone 3 and is directed towards the supra-acetabular region 26 of the hipbone 10.

Next the rod 1 is inserted into the threaded hole 12 from the lateral side of the femoral bone 3.

Then the shank 19 of the spherical head 18 in assembly with the plate 15 is introduced into the threaded hole 20, and the check clamp 21 is fitted into the openings 23 (Fig. 3) and the annular groove 22.

Further on, the shank 13 (Fig. 1) is rotated to move the rod 1 lengthwise its axis 0_1 towards the hipbone 10 until the plate 15 thrusts against the hipbone 10.

Thereupon a hole is made, using an osteotome, in the cortical layer of the hipbone 10 at the place of contact of the bent-out narrower end 29 of the plate 15 with the hipbone 10. It is most common practice to make the aforesaid hole for inserting the narrower end 29 of the plate 15 thereinto with the aid of a template, which is also used for marking out the holes 27 (Fig. 5) in the plate 15. Then the bent-out narrower end 29 of the plate 15 is fitted into said hole and the plate 15 is forced against the hipbone 10 (Fig. 1). Next the holes for wood-screws 28 (Fig. 5) or dowel pins are made in the hipbone 10 (Fig. 1) at the places of location of the holes 27 (Fig. 5) in the plate 15, and the plate 15 is fastened on the hipbone 10 (Fig. 1) by means of the woodscrews 28 or dowel pins. Further rotation of the shank 13 makes the rod 2 move along the axis 0_1 of the rod 1 laterally so as to establish the articular interstice 11, the amount of which depends on the distance SM, H is X-ray monitored and should be adjusted within 2 and 5.5 mm individually for every particular patient in order to provide for most advantageous conditions for hip joint restoration.

Thereupon the shank 19 of the spherical head 18 is fixed in the axial hole 20 with the aid of the check clamp 21, while the rod 1 is fixed in the threaded hole 12

of the rod 2 with the aid of the cotter pin 25.

Then the proposed endoappliance for hip joint restoration is checked, on an operating table, for correct positioning and operation by forced movements of the lower limb, i.e., flexion-extension, abduction-adduction, and rotation.

Thereupon the surgical wound is stitched up in layers, an appropriate drain is established, and an aseptic dressing is applied.

Mobility of the lower limb is ensured immediately after surgery. The patient is permitted to stand on the thirteenth or fourteenth day after alleviation of pain resulting from aseptic inflamation. The lower limb operated upon may be loaded on the twentieth day after surgery by, e.g., performing bicycle exercises on a veloergometer.

The proposed endoappliance for hip joint restoration operates as follows.

The vertical load exerted by patient's mass is transmitted through the articulated joint to the rod 1 (Fig. 1) and further on through said rod to the rod 2 and is distributed over the length L of the portion of the femoral bone 3 which is situated in the latter bone, which reduces the specific load on the osseous tissue of the femoral bone 3 to a minimum value at which said tissue experiences no deformations causative of pathologies.

Such an arrangement of the rod 1 makes it possible to release the hip joint of the effect of vertical loads and of a compressive effect of the muscles, thereby providing for the articular interstice 11 and affording favourable conditions for hip joint restoration under which the nature of the loads applied to the lower limb corresponds to the physiological loads exerted upon a sound hip joint.

In this case mobility of the hip joint, that is,

the amount of angular displacement of the femoral bone 3 is increased as compared to the heretofore-known constructions of endoapparatus.

During rotation the femoral bone 3 performs angular motion about the axis SN passing through the centre S of the sperical head 18, and through the centre N of the head 8 of the femoral bone 3 within the whole scope, which is close to the amount of angular displacement of the head of a sound hip joint. In this case, the amount h of the articular interstice 11 remains invariable irrespective of the hip joint position.

During abduction-adduction of the lower limb the femoral bone 3 performs angular motion in the frontal plane, and the centre N of the head 8 of the femoral bone 3 is free to perform angular motion about the centre (fulcrum) S of the articulated joint of the rod 1, i.e., along a circular arc having a radius SN, the magnitude of said arc being restricted to the magnitude of a solid angle of the spherical recess 17 and is equal to about 40 degrees. The amount H of the articular interstice 11 is limited largely to the length of the coxofemoral ligament.

During flexion-extension of the lower limb the femoral bone 3 performs angular motion in the sagittal plane about an axis arranged substantially parallel to the frontal plane and passing through the centre (fulcrum) S of the spherical head 18, i.e., along a circular arc having a radius SN, the magnitude of said arc being not restricted by the articulated joint so that it can amount to 90 degrees and depends only on the extent of injury of ligamentary-muscular apparatus of the patient's hip joint. In this case the amount h of the articular interstice 11 changes only at the edges of the cotyloid cavity 9, while remaining practically invariable in the middle portion of said cavity irrespective of the position assumed by the femoral bone 3.

According to an embodiment of the construction arrangement of the endoappliance for hip joint restoration as presented in Fig. 6, a rod 30 capable of sustaining loads equal to the maximum loads exerted upon the patient's lower limb, is articulated, through one of its ends, to the means for holding it to the hipbone 10 with a possibility of rotating about two mutually square axes of angular displacements of the femoral bone 3 during abduction-adduction and rotation of the lower limb. The other end of the rod 30 is articulated to the means for its holding to the femoral bone 3 for angular displacements of the femoral bone during flexion-extension of the lower limb.

Used as the means for holding to the femoral bone 3 is a rod 31 adapted for insertion into the femoral bone 3 substantially on the axis of the diaphysis 4 and arranged at an angle α to the rod 30, which is substantially equal to the cervicodiaphyseal angle of the femoral bone 3. The rod 3 is similar to the rod 2 as for its construction arrangement (Fig. 1).

Articulated joint between the rods 30 (Fig. 6) and 31 enables the latter to rotate about an axis coplanar with the axes $0_1'$ and 0' of the respective rods 30 and 31 and arranged at an angle β to the axis 0' of the rod 31, which angle provides for setting of the fulcrum of the articulated joint between the rods 30, 31, during implantation of the endoappliance, to a position wherein said axis passes substantially through the centre N_1 of the head 8 of the femoral bone 3.

Such an articulated joint between the rods 30 and 31 enables one to completely rule out any contact of the head 8 of the femoral bone 3 with the surface of the cotyloid cavity 9 irrespective of the position assumed by the femoral bone during flexion-extension of the lower limb, such being the most characteristic, important, and

frequently repeated motion of the lower limb. Thus, ruling out of such a contact provides favourable conditions for hip joint restoration. In this case flexion-extension of the lower limb, with the use of the proposed endoappliance for hip joint restoration, is effected within a whole volume, which is close to the magnitude of the angle of flexion-extension of the lower limb with a sound hip joint, said angle amounting to 140 degrees.

In an embodiment of the endoappliance for hip joint restoration as shown in Fig. 6, an articulated joint between the rods 30 and 31 is shaped as a plain bearing having a cylindrical seating face. To this end, a hole 33 is made in a clubbed end 32 of the rod 31, which is located outside the femoral bone 3, the axis of said hole being coplanar with the axes 0_1 and 0' of the respective rods 30 and 31 and being arranged at the angle β to the axis 0' of the rod 31. The angle β may lie within 76 and 90 degrees, while its magnitude is selected individually for every particular patient against, e.g., an X-ray photo of the hip joint. A cylindrical-surface shell 34 is rotatably fitted in the hole 33. To restrict an axial motion of the shell 34 in one direction, a collar 35 is therein made on one side, said collar having its outside diameter in excess of the diameter of the hole 33.

To restrict an axial travel of the shell 34 in the opposite direction, a ring 36 is fixed in position with the aid of, e.g., a threaded joint, on the other side of the shell 34, said ring having its outside diameter exceeding the diameter of the hole 33.

The shell 34 is so connected to the rod 30 that the latter is free to move lengthwise its axis $0_1'$ and be fixed in a preselected position by virtue of a threaded joint. A threaded hole 37 is made in the shell 34, whose

axis makes up an angle γ with the axis of its outer cylindrical surface, said angle γ being equal to $\alpha - \beta$.

The threaded hole 37 accepts one of the ends of the rod 30. To fix the rod 30 in a predetermined position, a tapered hole 38 is made therein, arranged along its axis $0_1'$, a stop sleeve 39 being thread-fitted in said hole. In addition, three longitudinal slots 40 (Fig. 7) are provided in the rod 30, arranged lengthwise the tapered hole 38, and three elastic tabs 41 are established between said slots, which are adapted for locking the threaded joint between the shell 34 and the rod 30.

The means for holding the endoappliance to the hipbone 10 (Fig. 6) in the hereindescribed embodiment of the endoappliance for hip joint restoration is shaped as a plate 42 similar in configuration to the plate 15 as shown in Fig. 1 and having two holes for the screws 28 (Fig. 8). The sole difference between the plates resides in that the plate 42 (Fig. 6) is articulately associated with the rod 30 within a possibility of rotation about two substantially mutually square axes by virtue of two plain bearings having cylindrical seating faces.

To this aim, provision is made for two hangers 43, 44 (Fig. 8), which are interconnected, through one of their end, by means of an axle 45 (Fig. 6), which is arranged substantially square with the plane passing through the axes 0' and $0_1'$ of the respective rods 30 and 31. The hanger 43 is articulated to the plates 42 through its other end 46, which is in fact a shaft rotatably mounted in a hole 47 made in an extension 48 of the plate 42. To ensure against axial displacement of the hanger 43 its end 46 is fixed in place in the hole 47 by means of an arcuate lockpin 49. The axis of the hole 47 is coplanar with the axes $0_1'$ and 0' of the respective rods 30, 31 and is substantially square with the axis S_1.

The other hanger 44 (Fig. 8) is rigidly coupled,

through its other end, to the rod 30 (Fig. 6) with the aid of a separable joint of the horse taper type. To this effect, a tapered hole 50 (Fig. 6) is made in the hanger 44 (Fig. 8), which receives an end 51 of the rod 30, said end having a tapered surface, whose taper is equal to the taper of the hole 50. Besides, the rod 30 has an axial hole 52, and the hanger 44 (Fig. 8) is provided with a threaded hole 53 coaxial with the hole 52, both of said holes accepting a coupling screw 54.

The articulated joint between the rods 30 and 31 is made as a plain bearing with a tapered seating face, which rules out the possibility of jamming of the shells of said bearing. An alternative embodiment of the articuated joint between the rods 30 and 31 is shown in Fig. 9. A hole 55 is made in the clubbed end 32 of the rod 31, the inner face of said hole being established by the surface of two cone frustums adjoining each other with their lesser bases. The outer surface of a shell 56 fitted on said hole 55 and the inner face of the hole 55 are congruent with each other, both surfaces have the same taper, and the cone generator of each taper surface makes up an angle with the axis of rotation of said surface, ranging from 24 to 36 degrees. The shell 56 is composed of two pieces interconnected through a screw 57.

Such a construction arrangement of the articulated joint between the rod 30 (Fig. 6) and the rod 31 makes it possible to reduce the size of the connecting clubbed end 32 or the rod 31 without affecting its bearing capacity, which is of paramount importance in treatment of the hip joint in children.

A surgical procedure for implantation of the proposed endoappliance for hip joint restoration as represented in Figs. 6, 7, 8, 9 is carried out substantially in the same way as the procedure for implanting the endoappliance as per Figs. 1, 2, 3, 4, 5.

The rod 31 in assembly with the rod 30 is inserted into the medullary canal 5 (Fig. 6) of the femoral bone 3. A place for installing the plate 42 in assembly with the hangers 43, 44 (Fig. 8), using a template, so that the holes 52 (Fig. 6) and 53 be coaxial. The rod 31 is withdrawn, in the threaded hole 37 of the shell 34, into an extreme position towards the distal end of the neck of the femoral bone 3.

Then the plate 42 in assembly with the hangers 43 and 44 (Fig. 8) is fixed in place on the hipbone 10.

Using the coupling screw 54 (Fig. 6) the rod 30 is connected to the hanger 44 (Fig. 8), whereupon the rod 30 (Fig. 6) is rotated so as to make the rod 31 travel along the axis $0'_1$ of the rod 30 together with the femoral bone 3, thus establishing a required amount h of the articular interstice 11. Thereupon the rod 30 is fixed in position in the shell 34 by rotating the stop sleeve 39 (Fig. 7).

The proposed embodiment of the endoappliance for hip joint restoration as illustrated in Figs. 6, 7, 8 enables one to completely release the hip joint of the effect of vertical loads and of a compressive effect of the muscles. The articulated joint between the rods 30 (Fig. 6) and 31 enables the lower limb, to rotate during its flexion-extension, about the axis N_1M_1 passing through the centre N_1 of the head 8 of the femoral bone 3, which makes it possible to completely rule out any contact of the head 8 of the femoral bone 3 with the surface of the cotyloid cavity irrespective of the position by the femoral bone 3 during flexion-extension of the lower limb.

Considered hereinbelow are some examples of clinical application of the proposed endoappliance for hip joint restoration.

There may serve as indication for surgical treatment with the use of the proposed endoappliance for

hip joint restoration the following diseases: dysplastic, degenerative-dystrophic and posttraumatic affections of the hip joint in children, adolescents, and adults, the sole exception being coxarthrosis of the inflammatory etiology. The age span of the patients ranged from 4 to 60, predominantly with the third degree of destruction of the articular bone ends.

The only contraindication for use of the present endoappliance is coxarthrosis of the inflammatory etiology. All the hip joint affections were classified into the following seven groups as for the clinico-radiological characteristic of the pathological process:

- congenital disclocation of the hip joint;
- dysplastic and degenerative-dystrophic diseases of the hip joint in children, exhibiting the third degree of destruction of the proximal femur end (Perthes' disease, juvenile epiphysiolysis);
- coxarthrosis without cystic degeneration;
- coxarthrosis involving cystic degeneration;
- aseptic necrosis;
- dysplastic coxarthrosis (in adults only);
- posttraumatic coxarthrosis.

Surgery for implantation of the proposed endoappliance was performed in two versions depending upon the initial biomechanical situation in the hip joint involved.

Version I

The endoappliance was implanted without reconstructive intervention on the articular bone ends. In this case distraction of the hip joint till a required amount of the articular interstice was attained and was carried out without cutting the hip joint capsule open.

Version II

Surgery started from reconstructive intervention on the articular bone ends (i.e., correctant osteotomy of

Nine months after surgery and upon active loading of the hip joint the latter was practically formed, while the amount of the articular interstice was retained within 3 and 4 mm.

The functional capabilities of the lower limb and the range of motion were featured by the following parameters: angle of flexion-extension, 90 to 95 degrees; angle of abduction, 25 degrees; angle of adduction, 15 degrees; angle of rotation, within a whole range.

Two years and eight months after surgery the endoappliance for hip joint restoration was removed and the hip joint regained its function completely.

No pathological changes in the hip joint were detected on a control X-ray pattern taken two years after removel of the endoappliance, upon an unlimited loading of the hip joint.

Similar surgical procedures were carried out in another ten patients with congenital hip dislocation, positive results being in all cases. Only one of the surgeries was complicated with postoperative seroma.

Example 2

A male patient, 27, a ballet dancer suffering from bilateral eystic deforming coxarthrosis with third-degree destruction and pain syndrome underwent surgery for implantation of the proposed endoappliance for hip joint restoration in the right lower limb, as presented in Figs. 1 to 5, the magnitude of the angle α being 140 degrees.

Surgery was performed without cutting the hip joint capsule open. Upon implanting the endoappliance the amount of the articular interstice was equal to 1 or 2 mm.

The postoperative period was uneventful. Six months after surgery and upon active loading of the lower limb the hip joint regained its mobility practically to the full extent.

The functional capabilities of the lower limb and the range of movements are characterised by the following parameters: angle of flexion-extension, 100 degrees, angle of abduction, 15 to 30 degrees, angle of adduction, 15 to 20 degrees; angle of rotation, within a whole range.

One year after surgery a control X-ray pattern detected a clear-cut contour of the hip joint exhibiting the amount of the articular interstice of from 1 to 2 mm. Three years later the endoappliance was withdrawn and the right hip joint regained its function fully.

In another year a similar surgical procedure was performed on the patient's left hip joint.

Similar favourable-outcome surgical procedures were carried out in another twelve patients affected by cystic coxarthrosis with third-degree destruction and pain syndrome. Only two patients operated upon developed postoperative complications in the form of seroma.

Example 3

A male patient, 7, affected by Perthes' disease with destruction of degree III and pain syndrome of degree II was operated for implantation of the proposed endoappliance for hip joint restoration in the left lower limb, as presented in Figs. 6, 7, 8, featuring the angle α equal to 130 degrees. The joint capsule was not cut open during implantation. As a result of distraction the articular interstice was set to be from 3 to 4 mm.
In two months after surgery and after five weeks of functional loading the boundaries between the fragments of the femoral head that had been clearly recognized, practically disappeared. The epiphyseal growth zone was clearly visible. A predetermined amount of the articular interstice did not change, as well as the position of the central of the femoral head; no symptoms of destablilization of the whole structure were seen.

In 3.5 months after surgery and after 11 weeks of functional loading (during which period the child attended school and kept a routine way of life), an integrated epiphyseal contour was practically established. Reconstructure foci were clearly found in the femoral neck against a background of precedent cystic changes. The spots of destruction lost their clear-cut outlines and acquired a radiographic appearance corresponding to that of the femoral neck.

In eight months after surgery and after seven months of functional loading of the lower limb the epiphysis regenerated completely and acquired a contour approximating the shape of the epiphysis of the sound right hip joint.

One year after surgery the endoappliance was removed, and the left hip joint regained its function practically completely.

In a year after removal of the endoappliance a control X-ray pattern displayed retained normal width (amount) of the articular interstice and stabilized epiphyseal contour. Patient's physical activities were not restricted by any special regimen of everyday life.

Similar surgical procedures were carried out in another nine patients affected by Perthes' diseases, positive results being attained in all cases without postoperative complications.

Example 4

A male patient, 13, suffering from juvenile epiphysiolysis of the left femoral head of degree II destruction and pain syndrome was subjected to surgery for implanting the endoappliance presented in Fig. 6, the magnitude of the angle α being 130 degrees.

No cutting of the joint capsule open was performed during implantation. As a result of distraction the width of the articular interstice was increased up to

12 mm.

In three weeks after surgery the following radiologic aspects were observed: further dislodging of the epiphysis was arrested, the growth zone became denser, its loose texture disappeared, the destruction area in the femoral neck at the edge of the growth zone got filled with the bone density regenerate.

Three months after surgery and after two months of functional loading of the lower limb the amount of the articular interstice remained unaffected, the cervicodiaphyseal angle was equal to 130 degrees. In ten months after surgery and nine months after normal functional loading there were observed complete restoration of the femur- and a clear-cut densified contour of the cotyloid cavity. The amount of the articular interstice was equal to 6 or 8 mm as seen on an X-ray pattern. Complete reunion of the epiphysis ensued. The radiographic appearance corresponded to a typical picture of the proximal femur end. The functional capabilities of the lower limb operated upon were realized in a full scope. The patient retained ability to self-service completely within the entire treatment period; he attended school and kept a routine way of life.

One year after surgery the endoappliance was removed. Complete anatomical and functional rehabilitation of the hip joint was observed.

Similar surgical procedures were carried out in another four patients affected by juvenile epiphysiolysis, favourable results being attained in all cases without postoperative complications.

Example 5

A male patient, 39, a car driver suffering from aseptic necrosis of the right femoral head with degree III destruction and pain syndrome was subjected to surgery for implanting the endoappliance as illustrated in Figs, 1

through 5, having a cervicodiaphyseal angle α equal to 130 degrees. The operative intervention was performed without cutting the joint capsule open and involved no additional surgical manipulations whatever on the joint ends articulated together. The amount of the articular interstice after distraction was equal to 6 or 7 mm.

Four months after surgery and after three months of graduated loading of the lower limb the femoral head lost a sclerosed background, while its defect was presented on an X-ray pattern as a shadow characteristic of a spongy bone but was devoid of its clear-cut picture.

One year after surgery the amount of the preset articular interstice remains unaffected, i.e., 5 to 7mm. The femoral head densified its contour started to regain its continuity.

In four years after surgery the femoral head regained its contour completely except for a hardly detectable marginal spot measuring 0.2 x 0.3 cm.

Six years after surgery and after four years of routine loading of the lower limb complete utilization of the necrotized areas of the femoral head ensued, while the lost mass of the femoral head and a normal radiographic appearance of the articulated ends of the hip joint were restored. The patient regained ability to perform light jobs one year and nine months after surgery, while another year later he resumed his former occupation as a car driver.

Similar surgical interventions were carried out in another 14 patients suffering from aseptic necrosis of the femoral head, favourable results being attained in all cases. Only two cases exhibited postoperative complications as fistulas.

Example 6

A male patient, 43, an electrician affected by posttraumatic coxarthrosis in the form of an inveterate

nonrepositioned supraposterior dislocation of the right femoral bone involving evulsion of the margin of the cotyloid cavity with degree II destruction and degree III pain syndrome was subjected to surgery for implantation of the endoappliance presented in Figs. 6, 7, 8, featuring the angle α equal to 130 degrees.

The femoral head was repositioned by the open technique, that is by cutting the joint capsule open. The postdistraction width of the articular interstice was within 5 and 8 mm.

In fifteen days after surgery the functional capabilities of the lower limb operated upon were quite adequate, viz., angle of active flexion, 90 degrees, angle of abduction, 27 degrees, angle of rotation, in the norm.

In twenty-one days after surgery the patient was permitted to walk with crutches without supporting on the lower limb operated upon while in three months after surgery complete loading of the lower limb was allowed. The patient could look after himself and the pain syndrome disappeared.

One year after surgery the functional capabilities of the lower limb operated upon were found to be excellent. No painful syndrome whatever. The amount of the articular interstice remained within the limits of 5 or 6 mm. There was observed a positive aspect of structural reconstruction of the subchondral segment of the femoral head and neck. The margin-together foci of osteoporosis that had occupied the principal mass of the head, nearly disappeared, the contours of the femoral head and of the cotyloid cavity were defined clearly.

One year and five months after surgery the endoappliance was withdrawn. An X-ray pattern displayed complete restoration of the shape and radiographic appearance of the hip joint.

Similar surgical procedures were carried out in

another nine patients suffering from posttraumatic coxarthrosis, positive results being attained in all cases. Only two patients developed fistulas in the postoperative period.

Industrial Applicability

The proposed endoappliance for hip joint restoration is applicable in orthopedics and traumatology for treatment of pathologies associated with the hip joint locomotordys-function. The present endoappliance can be applied to good advantage for treatment of degenerative-dystrophic diseases of the hip joint (coxarthrosis) of and etiology, such as dysplasia, juvenile epiphysiolysis, cystose dystrophy, aseptic necrosis of the femoral head, Perthes' disease reumatoid or tuberculous affection of the hip joint, traumatic lesions and congenital hip joint dislocation in children and adults. Treatment of the aforelisted diseases proves to be most successful, when applying the proposed endoappliance for hip joint restoration, in the initial stages thereof.

CLAIMS:-

1. An endoappliance for hip joint restoration, comprising a first rod capable of sustaining loads that are substantially equal to the maximum loads taken up by patient's lower limb, the rod being connected through one of its ends to a means for holding the rod to a femoral bone whereas the other end thereof is articulated to a means for holding the rod to a hipbone, characterised in that the means for holding the rod to the femoral bone is shaped as a second rod adapted to be fitted inside the femoral bone substantially along the axis of a diaphysis and arranged at an angle to the first rod, the angle being substantially equal to the cervicodiaphyseal angle.

2. An endoappliance for hip joint restoration as claimed in claim 1, wherein the length of the second rod portion situated inside the femoral bone is substantially equal to half the length of patient's femoral bone.

3. An endoappliance for hip joint restoration, as claimed in claim 2, wherein a threaded portion is provided along the length of the second rod inside the femoral bone.

4. An endoappliance for hip joint restoration as claimed in claims 1, or 2, or 3, wherein the first rod is associated with the second rod with the aid of a threaded joint which enables the first rod to move lengthwise along its own axis.

5. An endoappliance for hip joint restoration as claimed in claim 4, wherein a tapered hole is provided at an end of a first rod facing the threaded joint, which hole is arranged along the rod axis, and at least three

longitudinal slots are provided, arranged lengthwise along the tapered hole, and a stop sleeve is fitted in the tapered hole with the aid of a threaded joint.

6. An endoappliance for hip joint restoration as claimed in any of claims 1 to 5, wherein the first and the second rods are interconnected through an articulated joint capable of rotating about an axis coplanar with the axes of the both rods and arranged at such an angle to the axis of the second rod that ensures setting of the articulated joint fulcrum, during the implementation of the endoappliance to a position, wherein it passes substantially through a centre of a head of the femoral bone.

7. An endoappliance for hip joint restoration as claimed in claim 6, wherein the angle between the fulcrum of the articulated joint and the axis of the second rod makes up an angle of from 76 to 90 degrees.

8. An endoappliance for hip joint restoration as claimed in claim 6 or 7, wherein the articulated joint is shaped as a plain bearing having a tapered seating face.

9. An endoappliance for hip joint restoration substantially as hereindescribed with reference to the accompanying drawings.